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10.0 510(k) SUMMARY

Coapt Systems is providing a summary of the safety and effectiveness information available for the ENDOTINE TransBleph™ 3.0/3.5 Device. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

SPONSOR/APPLICANT NAME AND ADDRESS

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CONTACT INFORMATION

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DATE OF PREPARATION OF 510(K) SUMMARY

October 8, 2004

DEVICE TRADE OR PROPRIETARY NAME

ENDOTINE TransBleph™ 3.0/3.5 Device

DEVICE COMMON OR CLASSIFICATION NAME

Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	888.3040
Class:	II
Product Code:	HWC

IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Name of Manufacturer	510(k) or PMA Number
ENDOTINE TransBleph™ Device	Coapt Systems, Inc	K040740
ENDOTINE Forehead™ Devices	Coapt Systems, Inc.	K014153 K023992
ENDOTINE Chin™ Devices	Coapt Systems, Inc.	K033524

DEVICE DESCRIPTION

The ENDOTINE TransBleph™ 3.0/3.5 Device consists of a bioabsorbable implant, an insertion tool, and stainless steel drill bit. The device implant is a soft tissue fixation platform that is anchored in the cranial bone. The insertion tool and the drill bit are sterilized together with the implant device in a plastic tray.

INTENDED USE STATEMENT

The ENDOTINE TransBleph™ is intended for use in subperiosteal browplasty surgery. The ENDOTINE TransBleph™ is specifically indicated for use to fixate the subdermis to the cranial bone in browplasty.

SUBSTANTIAL EQUIVALENCE

In review of the device description, predicate comparison and design control activities incorporated in this submission, no significant new issues of safety or effectiveness have been raised for the Modified TransBleph™ 3.0/3.5 Device. The Modified Device meets all internal functional performance requirements.

Based on the design, materials, fundamental technology, intended use, and performance evaluations, Coapt Systems believes the proposed ENDOTINE TransBleph™ 3.0/3.5 Device is substantially equivalent to the unmodified predicate device, the ENDOTINE TransBleph™ Device, currently marketed under the Federal Food, Drug and Cosmetic Act. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Mr. Bankim Mahta
Vice President, Operations, QA and RA
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Atlo, California 94566

Re: K042796
Trade/Device Name: ENDOTINE TransBleph™ 3.0/3.5 Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: October 6, 2004
Received: October 7, 2004

Dear Mr. Mahta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):	Not yet assigned
Device Name:	ENDOTINE TransBleph™ 3.0/3.5 Device
Indications For Use:	The ENDOTINE TransBleph™ is intended for use in subperiosteal browplasty. The ENDOTINE TransBleph™ is specifically indicated for use to fixate the subdermis to the frontal bone.

Prescription Use __X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042796